

CLAIMS

WE CLAIM:

- 5 1. A dosage form comprising
 - (a) a membrane defining a compartment, the membrane having an exit orifice formed or formable therein and at least a portion of the membrane being semipermeable;
 - (b) an expandable layer located within the compartment remote from
10 the exit orifice and in fluid communication with the semipermeable portion of the membrane;
 - (c) a delay layer located adjacent the exit orifice;
 - (d) a drug layer located within the compartment between the delay layer and the expandable layer; and
 - 15 (e) an interface boundary between the delay layer and the drug layer, the interface boundary being convex in shape relative to the exit orifice.
2. The dosage form of Claim 1 wherein the delay layer and the drug layer are formed by a compression sequence in which the delay layer is compressed
20 into its form prior to the drug layer being compressed into its form.
3. The dosage form of Claim 1 wherein:
the delay layer exhibits a higher viscosity than the drug layer when both are subjected to the same level of hydration.
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4. The dosage form of Claim 1 wherein:
the viscosity of the delay layer is higher than the viscosity of the drug layer at equivalent aqueous saturation levels.

5. A dosage form comprising:

(a) a membrane defining a compartment, the membrane having an exit orifice formed or formable therein and at least a portion of the membrane being semipermeable;

5 (b) an expandable layer located within the compartment remote from the exit orifice and in fluid communication with the semipermeable portion of the membrane;

(c) a delay layer located adjacent the exit orifice;
a drug layer located within the compartment between the delay layer and the expandable layer; and

10 (d) the delay layer having a higher viscosity than the viscosity of the drug layer when both are subjected to the same level of hydration.

6. The dosage form of Claim 5, further comprising:

15 an interface boundary between the delay layer and the drug layer, the interface boundary being convex in shape relative to the exit orifice.

7. The dosage form of Claim 6 wherein the delay layer and the drug layer are formed by a compression sequence in which the delay layer is compressed

20 into its form prior to the drug layer being compressed into its form.

8. A dosage form comprising

(a) a membrane defining a compartment, the membrane having an exit orifice formed or formable therein and at least a portion of the membrane being semipermeable;

25 (b) an expandable layer located within the compartment remote from the exit orifice and in fluid communication with the semipermeable portion of the membrane;

(c) a delay layer located adjacent the exit orifice; and

30 (d) a drug layer located within the compartment between the delay layer and the expandable layer;

(e) the largest component by weight of the delay layer having a viscosity when subjected to an aqueous medium greater than the viscosity of the largest component by weight of the drug layer in the same aqueous medium at the same level of hydration.

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9. A method of reducing tunneling of a drug layer through a delay layer of a delayed release dosage form during a delay period, the dosage form having a compartment for containing the delay layer and the drug layer prior to release and an exit orifice for releasing the material of the delay and drug layers, the delay layer being disposed between the drug layer and the orifice, the method comprising:

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(a) formulating the delay layer and the drug layer such that the viscosity of the delay layer remains higher than the viscosity of the drug layer during the delay period.

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10. A method of controlling the release of a drug layer from a delayed release dosage form, the dosage form having a compartment for containing a delay layer and the drug layer prior to release and an exit orifice for releasing the material of the delay and drug layers, the delay layer being disposed between the drug layer and the orifice, the method comprising:

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(a) formulating the delay layer and the drug layer such that the viscosity of hydrated portions of the delay layer within the compartment remains higher than the viscosity of the hydrated portions of the drug layer within the compartment during a substantial portion of the time that the delay layer inhibits the release of the drug layer from the compartment.

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11. A method of controlling the release of a drug layer from a delayed release dosage form, the dosage form having a compartment for containing a delay layer and the drug layer prior to release and an exit orifice for releasing the material of the delay and drug layers, the delay layer being disposed between the drug layer and the orifice, the method comprising:

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(a) formulating the delay layer and the drug layer such that the general viscosity of the delay layer when hydrated is greater than the general viscosity of the drug layer when hydrated to the same level of hydration.

5 12. The method of Claim 9, wherein the difference during the desired delay period between the viscosity of the delay layer and the viscosity of the drug layer is sufficiently high so as to reduce tunneling of the drug layer through the delay layer.

10 13. The method of Claim 9 wherein premature tunneling of the drug layer through the delay layer is reduced.

14. The method of claim 10 wherein premature tunneling of the drug layer through the delay layer is reduced.

15 15 The method of Claim 11 wherein premature tunneling of the drug layer through the delay layer is reduced.

20 16. The method of Claim 9, wherein the rate of tunneling of the drug layer through the delay layer is reduced over the rate of tunneling that occurs when the difference between the viscosity of the delay layer and the viscosity of the drug layer is approximately equal.

25 17. The method of Claim 10 wherein the rate of tunneling of the drug layer through the delay layer is reduced over the rate of tunneling that occurs when the difference between the viscosity of the delay layer and the viscosity of the drug layer is approximately equal.

30 18. The method of Claim 11 wherein the rate of tunneling of the drug layer through the delay layer is reduced over the rate of tunneling that occurs when the difference between the viscosity of the delay layer and the viscosity of the drug layer is approximately equal.

19. The method of Claim 9 wherein after the delay period, drug from the drug layer is released from the dosage form for a period of time in a continuous and substantially ascending rate.

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20. The method of Claim 13 wherein after the delay period, drug from the drug layer is released from the dosage form for a period of time in a continuous and substantially ascending rate.

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21. The method of Claim 16 wherein after the delay period, drug from the drug layer is released from the dosage form for a period of time in a continuous and substantially ascending rate.

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22. Method of Claim 9 wherein the viscosities of the drug layer and the delay layer are between 70 and 350 cps.

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23. A dosage form comprising

(a) a membrane defining a compartment, the membrane having an exit orifice formed or formable therein and at least a portion of the membrane being semipermeable;

(b) an expandable layer located within the compartment remote from the exit orifice and in fluid communication with the semipermeable portion of the membrane;

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(c) a delay layer located adjacent the exit orifice;

(d) a drug layer located within the compartment between the delay layer and the expandable layer; and

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(e) the major component of the delay layer having a viscosity when subjected to an aqueous medium greater than the viscosity of the major component of the drug layer in the same aqueous medium at the same level of hydration.

24. The dosage form of Claim 5 wherein the viscosity of the delay layer is above 150 cps in an aqueous medium.
- 5 25. The dosage form of Claim 5 that, after oral administration, provides a prolonged substantially ascending drug release rate.
26. The dosage form of Claim 8, further comprising:
an interface boundary between the delay layer and the drug layer, the interface boundary being convex in shape relative to the exit orifice.
- 10 27. The dosage form of Claim 26 wherein the delay layer and the drug layer are formed by a compression sequence in which the delay layer is compressed into its form prior to the drug layer being compressed into its form.
- 15 28. The dosage form of Claim 1 wherein the drug layer comprises a drug selected from the group of cyclobenzaprine, amitriptyline imipramine and desipramine.
29. The dosage form of Claim 1 wherein the drug layer comprises
20 cyclobenzaprine and that provides a cyclobenzaprine plasma concentration of 6 to 8 ng/ml three to four hours after dosing and approximately 8 to 12 ng/ml eighteen to twenty hours after oral administration in a human.
30. A method of controlling the release via an exit orifice of delay layer
25 materials and drug layer materials from a dosage form comprising a delay layer and a drug layer, the method comprising disposing a delay layer between the drug layer and the exit orifice with the delay layer having a viscosity higher than the viscosity of the drug layer.
- 30 31. A method of controlling the release via an exit orifice of delay later materials and drug layer materials from a dosage form comprising a delay layer and a drug layer, the method comprising disposing a delay layer between the

drug layer and the exit orifice with the principal component of the delay layer having a viscosity higher than the viscosity of the principal component of the drug layer.

5 32. The dosage form of Claim 5, wherein the drug layer comprises a tricyclic amine.

33. The dosage form of Claim 32, wherein the drug layer comprises cyclobenzaprine.

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34. The dosage form of Claim 32, wherein the drug layer comprises amitriptyline.

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35. The dosage form of Claim 32, wherein the drug layer comprises imipramine.

36. The dosage form of Claim 32, wherein the drug layer comprises desipramine.

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37. A method of controlling the release of a drug layer from a delayed release dosage form, the dosage form having a compartment for containing a delay layer and the drug layer prior to release and an exit orifice for releasing the material of the delay and drug layers, the delay layer being disposed between the drug layer and the orifice such that an interface exists between the drug layer and the delay layer, the method comprising:

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 configuring the shapes of the drug layer and the delay layer such that the shape of the interface is substantially convex in relation to the exit orifice.

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38. The method of Claim 9 further comprising configuring the shape of the drug layer and the delay layer such that an interface exists between the drug layer and the delay layer and the interface is substantially convex in relation to the exit orifice.

- 39 The method of Claim 10 further comprising configuring the shape of the drug layer and the delay layer such that an interface boundary exists between the drug layer and the delay layer and the interface boundary is substantially
- 5 convex in relation to the exit orifice.